

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of:  
Alan G. BAXTER

Serial No.: 09/308,192

Filing Date: July 14, 1999

For: METHOD OF IMMUNOMODULATORY  
TREATMENT OF INSULIN  
DEPENDENT DIABETES MELLITUS  
USING MYCOBACTERIAL CELL  
WALL COMPOSITIONS (as amended)

Examiner: S. Devi

Group Art Unit: 1645

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**INFORMATION DISCLOSURE  
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. § 1.97 and § 1.98, Applicant submits for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. The Examiner is requested to make these documents of record.

Document numbers 1, 3-18 listed on the attached Form PTO/SB/08a/b were cited in the International Search Report directed to the counterpart international application; therefore, copies are not submitted herewith. Document numbers 2, 19-26 listed on the attached Form PTO/SB/08a/b were cited in a Partial European Search Report directed to a counterpart foreign application and have not been previously cited. Copies of the non-patent literature documents are submitted herewith. Also attached is a copy of an Office Action mailed on February 2, 2006, directed to the counterpart European application. The D10 document by McNeil et al. entitled, "Evidence for the

Nature of the Link between the Arabinogalactan and Peptidoglycan of Mycobacterial Cell Walls,” cited within the Action was previously cited in the International Search Report.

This Information Disclosure Statement is submitted with the filing of a Request for Continued Examination under § 1.114. Accordingly, no other submissions are required.

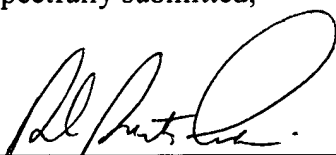
Applicant would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.

The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing (229752000600).

Dated: March 3, 2006

Respectfully submitted,

By   
Barry E. Bretschneider

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	09/308,192
				Filing Date	July 14, 1999
				First Named Inventor	Alan G. BAXTER
				Art Unit	1645
				Examiner Name	S. J. N. Devi
Sheet	1	of	2	Attorney Docket Number	229752000600

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U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	1.	US-4,152,423	5-1-1979	Adam et al.	
	2.	US-4,307,229	12-22-1981	Liav et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	3.	WO-96/00579-A	1-11-1996			
	4.	WO-96/26288-A	8-29-1996			
	5.	WO-94/16727-A	8-4-1994			
	6.	WO-87/02249-A	4-23-1987			
	7.	GB-2120548-A	12-7-1983			

\*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	8.	HIRSCHFIELD et al. (Feb 1990) "Peptidoglycan-Associated Polypeptides of Mycobacterium Tuberculosis," <i>J. Bacteriol.</i> 172(2): 1005-1013	
	9.	AZUMA et al. (Nov 1968) "Fractionation of Mycobacterial Cell Wall," <i>J. Bacteriol.</i> 96(5): 1885-1887	
	10.	BAXTER et al. (1994) "Mycobacteria Precipitate an SLE-like Syndrome in Diabetes-Prone NOD Mice," <i>Immunology</i> 83: 227-231	
	11.	SADELAIN et al. (May 1990) "Prevention of Type I Diabetes in NOD Mice by Adjuvant Immunotherapy," <i>Diabetes</i> 39(5), 583-587	
	12.	HARADA et al. (1990) "Prevention of Overt Diabetes and Insulitis in NOD Mice by a Single BCG Vaccination," <i>Diabetes Res. Clin. Pract.</i> 8: 85-89	
	13.	QIN et al. (1993) "Complete Freund's Adjuvant-Induced Tcells Prevent the Development and Adaptive Transfer of Diabetes in Nonbese Diabetic Mice," <i>J. of Immunol</i> 150(5): 2072-2080	
	14.	CHUGH et al. (1992) "Protective Efficacy of Different Cell-Wall Fractions of Mycobacterium Tuberculosis," <i>Folia. Microbiol (Praha)</i> 37(6): 407-412	
	15.	BEAUDET et al. (1983) "Stimulation of Non-Specific Anti-Tumor Resistance in the Mouse Using Cell Wall Preparations from Four BCG Substrains," <i>Ann. Immunol. (Paris)</i> 134C(2): 215-226	
	16.	DOCKRELL et al. (Oct 1996) "Induction of Th1 Cytokine Responses by Mycobacterial Antigens in Leprosy," <i>Infect. Immun.</i> 64(10): 4385-4389	
	17. ✓	McNEIL et al. (Oct 1990) "Evidence for the Nature of the Link Between the Arabinogalactan and Peptidoglycan of Mycobacterial Cell Walls," <i>J. Biol. Chem.</i> 265(30): 18200-18206	
	18.	BARNES et al. (Apr 1992) "Tumour Necrosis Factor Production in Patients with Leprosy," <i>Infect. Immun.</i> 60(4): 1441-1446	
	19. ✓	HAYASHI, Akira (1994) "Interferon-γ as a Marker for the Effective Cancer Immunotherapy with BCG-Cell Wall Skeleton," <i>Proc. Japan Acad</i> 70(10): 205-209	

Examiner Signature		Date Considered	
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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
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				Examiner Name	S. J. N. Devi
Sheet	2	of	2	Attorney Docket Number	229752000600

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20.	✓	CHIN et al. (1996) "Mycobacterium Cell Wall: An Alternative to Intravesical Bacillus Calmette Guerin (BCG) Therapy in Orthotopic Murine Bladder Cancer," <i>Journal of Urology</i> 156: 1189-1193	
21.	✓	MORALES et al. (May 1995) "Immunotherapy of an Experimental Adenocarcinoma of the Prostate," <i>Journal of Urology</i> 153: 1706-1710	
22.	✓	GRAY et al. (1975) "Brief Communication: Immunotherapy of Cancer: Tumor Suppression And Regression by Cell Walls of Mycobacterium Phiel Attached to Oil Droplets," <i>Journal of the National Cancer Institute</i> 55(3): 727-730	
23.	✓	SCHULTZ et al. (1995) "Effect of DETOX as an Adjuvant for Melanoma Vaccine," <i>Vaccine</i> 13(5): 503-508	
24.	✓	SHEHADAH et al. (March 1994) "Effect of Adjuvant Therapy on Development of Diabetes in Mouse and Man," <i>The Lancet</i> 343: 706-707	
25.	✓	QIN et al. (1993) "Complete Freund's Adjuvant-Induced T Cells Prevent the Development and Adoptive Transfer of Diabetes in Nonobese Diabetic Mice," <i>Journal of Immunology</i> 150(5): 2072-2080	
26.	✓	GAZDA et al. (Oct 1996) "Regulation of Autoimmune Diabetes: Characteristics of Non-Islet-Antigen Specific Therapies," <i>Immunology and Cell Biology</i> 74(5): 401-407	
27.	✓	Partial European Search Report directed to counterpart EP Application No. 97911956	
28.	✓	European Office Action mailed February 2, 2006, directed to counterpart EP Application No. 97911956.7	

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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